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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,916	10/10/2001	Peter M. Thule	US 1292/01 (VA)	4645

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/972,916	THULE, PETER M.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 9/20/2007.

Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Status if the Claims

Claims 1-15 and 17-21 are currently pending.

Claims 17-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/21/2004.

Claims 1-15 are examined herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 9/20/2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Diabetes May 1999, supplement— previously cited) as evidenced by Thule and Liu presentation at the ADA 59th Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting June 9-13, 1999, previously cited) as evidenced by Thule and Liu presentation at the American Society of Gene Therapy 2nd Annual Meeting, June 1999 (provided as Reference 4 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting of June 1998—previously cited) as evidenced by Thule and Liu presentation at the ADA 58th Annual Meeting, June 1998 (provided as Reference 2 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), for the reasons of record.

Response to Arguments

Applicant's arguments filed 9/20/2007 have been fully considered but they are not persuasive.

Applicants argue that the anticipation under 35 USC § 102(b) requires the disclosure in a single prior art reference of each element under consideration and that the single reference must disclose each element arranged as in the claim. Applicants contend that the Examiner is not relying on a single reference and the powerpoint presentation are not printed publications for the purposes of 35 USC §102(b) and that the presentations were transient in nature. Applicants also contend that the nucleotide numbering of the rat promoter elements are ambiguous and non-enabling. Applicant indicates that he was unable to discover an accepted authorized nomenclature for sequence numbering. Applicants also provide references which use different numberings for promoter sequences and the nucleotides identified in the presentation do not exactly correlate with the claimed sequences.

In response, Applicant is respectfully reminded that MPEP § 2131.01 indicates that normally, only one reference should be used in making a rejection under **35 U.S.C. 102**; however, a **35 U.S.C. 102** rejection over multiple references has been held to be proper when the extra references are cited to: (A) Prove the primary reference contains an "enabled disclosure;" (B) Explain the meaning of a term used in the primary reference; or (C) Show that a characteristic not disclosed in the reference is inherent. Regarding each of these elements, MPEP the following is indicated:

> When the claimed composition or machine is disclosed identically by the reference, an additional reference may be relied on to show that the primary

reference has an "enabled disclosure." *In re Samour,* 571 F.2d 559, 197 USPQ 1 (CCPA 1978) and *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (Compound claims were rejected under **35 U.S.C. 102(b)** over a publication in view of two patents. The publication disclosed the claimed compound structure while the patents taught methods of making compounds of that general class. The applicant argued that there was no motivation to combine the references because no utility was previously known for the compound and that the **35 U.S.C. 102** rejection over multiple references was improper. The court held that the publication taught all the elements of the claim and thus motivation to combine was not required. The patents were only submitted as evidence of what was in the public's possession before applicant's invention.).

Extrinsic evidence may be used to explain but not expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter. *In re Baxter Travenol Labs.*, 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991) (Baxter Travenol Labs. invention was directed to a blood bag system incorporating a bag containing DEHP, an additive to the plastic which improved the bag's red blood cell storage capability. The examiner rejected the claims over a technical progress report by Becker which taught the same blood bag system but did not expressly disclose the presence of DEHP. The report, however, did disclose using commercial blood bags. It also disclosed the blood bag system as "very similar to [Baxter] Travenol's commercial two bag blood container." Extrinsic evidence (depositions, declarations and Baxter Travenol's own admissions) showed that commercial blood bags, at the time Becker's report was written, contained DEHP. Therefore, one of ordinary skill in the art would have known that "commercial blood bags" meant bags containing DEHP. The claims were thus held to be anticipated.).

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.,* 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude

> a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See **MPEP § 2112 - § 2112.02** for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See **MPEP § 2124**.

Therefore, it is not inappropriate to rely on more than one reference for a rejection under 35 USC 102. In the instant case, the additional information can be relied upon for (B) to explain the meaning of a term used in the primary reference (here, to explain the meaning of the term Ad/$(GIRE)_3$ BP-1 2xfur or any other sequence element) ; and/or (C) to show that a characteristic not disclosed in the reference is inherent (e.g., the nucleotide sequences which the disclosed sequences comprise).

Applicant is also respectfully reminded that MPEP § 2128.01 indicates that a publicly displayed document where persons of ordinary skill in the art could see it and are not precluded from copying it can constitute a "printed publication," even if it is not disseminated by the distribution of reproductions or copies and/or indexed in a library or database. As stated in In re Klopfenstein, 380 F.3d 1345, 1348, 72 USPQ2d 1117, 1119 (Fed. Cir. 2004), "the key inquiry is whether or not a reference has been made publicly accessible.'" MPEP § 2128.01 further indicates that the court has noted that "an entirely oral presentation that includes neither slides

nor copies of the presentation is without question not a printed publication' for the purposes of 35 U.S.C.§ 102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a printed publication.'" 380 F.3d at 1349 n.4, 72 USPQ2d at 1122 n.4.

However, in the instant case, the presentations at issue were no "entirely oral" as slides of the presentation were shown.

MPEP § 2128.01 also indicates that in resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a "printed publication" under 35 U.S.C. 102(b), the court considered the following factors: "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." 380 F.3d at 1350, 72 USPQ2d at 1120. **Upon reviewing the above factors, the court concluded that the display "was sufficiently publicly accessible to count as a printed publication.'"** 380 F.3d at 1352, 72 USPQ2d at 1121 (Emphasis added).

In the instant case, although the information may have only been "transiently" available (as indicated by Applicant), it is noted that Applicant displayed the critical information in multiple presentations, as evidences by Applicants submitted material. Furthermore, the presentations appear to be given to audiences that include Applicants peers (such as the meeting at the ADA 58th Annual meeting (June 1998) and 59th Annual meeting (June 1999), as well as the American Society of Gene Therapy 2nd annual meeting (June 1999)), who would be expected to have expertise in the art. Furthermore, it is believed that there would not have been reasonable expectations that the material displayed would not be copied. Furthermore, the

information presented in the slides could have been easily copied by anyone attending any of the presentations.

Although Applicant was unable to discover an accepted authorized nomenclature for sequence numbering, it is noted at least one text book teaches nomenclature for sequence numbering. For instance, Genes & Genomes (Sanger and Berg, 1991) explicitly teaches,

> "The position of the first nucleotide in the transcript is designated +1, and those downstream of +1 (i.e., within the transcript unit), are given positive numbers (e.g., +16). Nucleotides upstream of +1 (nontranscribed sequences) are assigned negative numbers (e.g., -25)." (See page 462, second full paragraph).

Therefore, it was well known in the art (i.e., it was taught in a textbook), that the sequence numbering is relative to the transcriptional start site. Thus, one of ordinary skill in the art looking at the information presented by Applicant would recognize the sequence numbering as being relative to the transcriptional start site, which would make the sequences disclosed in the presentation relative to the transcriptional start site, as is the case in the instant application.

With respect to Applicants argument that the disclosed sequences do not exactly correlate with the claimed sequences, it is noted that the sequences at issue are expression regulatory elements that were each known in the prior art (i.e., they were not novel). That is, the nucleotide sequence which confers the function of element were known. The presentations given by the Applicant disclosed the arrangement of the known elements into particular configurations which conferred a specific function. Applicant's abstract, relied on as prior art, teaches a construct identified as the same construct of the instant claims and teaches the construct has all of the same functional characteristics as the claimed construct. The information that Applicant disclosed in the presentations further describes the construct and based on the information that was available

in the prior art, gave enough information to one of ordinary skill in the art (such as one attending the presentation) would be able to make the construct disclosed in the abstract, which would essentially be the same as the claimed construct as it would not only have the same function (as is indicated in the abstract) but also have the elements (sequences) critical for the function.

Therefore Applicant's arguments are not persuasive.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635